

WHAT IS CLAIMED:

1. An assembly for trapping arterial plaque against a vascular wall, comprising:

a radially outwardly deformable, tubular sheath having a proximal end and a distal end, said sheath to be introduced intravascularly and expanded against the vascular wall to trap the plaque therebetween.

2. The assembly of claim 1, further comprising:

a flexible elongated tubular member with an inner lumen extending therethrough from a proximal end of the tubular member to a distal end of the tubular member that is attached to the proximal end of the sheath.

3. The assembly of claim 2, wherein the tubular member is a catheter.

4. The assembly of claim 3, wherein the sheath is an integral part of the distal end of the catheter.

5. The assembly of claim 2, wherein the tubular member has a plurality of perforations formed near the distal end to allow fluid communication therethrough between the outside of the tubular member and the inner lumen.

6. The assembly of claim 1, wherein the sheath is comprised of a material selected from the group of materials consisting of polymers, cross-linked materials, and composites.

0902458-061901
10/29/2004 04:00:00

7. The assembly of claim 6, wherein the sheath material has a yield strength of between 50 psi and 300 psi.
8. The assembly of claim 7, wherein the sheath material has a break point tensile strength of over 2000 psi.
9. The assembly of claim 1, further comprising:
a radially outwardly deformable, tubular member disposed within the sheath between the distal end and the proximal end of the sheath to be expanded together with the sheath against the vascular wall.
10. The assembly of claim 9, wherein the deformable member is comprised of a material selected from the group of materials consisting of metals and thermoplastics.
11. The assembly of claim 9, wherein the deformable member is a wire mesh.
12. The assembly of claim 9, wherein the deformable member is a stent.
13. The assembly of claim 9, wherein the deformable member is a wire coil.
14. The assembly of claim 9, further comprising:

a flexible, elongated tubular member having an inner lumen extending therethrough from a proximal end of the tubular member to a distal end of the tubular member attached to the proximal end of the sheath to introduce the sheath with the
5 deformable member intravascularly.

15. The assembly of claim 14, wherein the tubular member is a catheter.

16. The assembly of claim 15, wherein the sheath is an integral part of the distal end of the catheter.

17. The assembly of claim 14, wherein the tubular member has perforations formed near the distal end to allow fluid communication therethrough between the outside of the tubular member and the inner lumen.

18. The assembly of claim 9, wherein the sheath is comprised of a material selected from the group of materials consisting of polymers, cross-linked materials, and composites.

19. The assembly of claim 19, wherein the sheath material has a yield strength of between 50 psi and 300 psi.

20. The assembly of claim 19, wherein the sheath material has a break point tensile strength of over 2000 psi.

0905450 "051901

21. The assembly of claim 9, wherein the deformable member is formed from a radiopaque material.

22. The assembly of claim 9, wherein the deformable member is formed from a shape memory alloy having a compressed state for placing within the unexpanded sheath and an expanded state for anchoring the sheath against the vascular wall, and exhibiting a radially outward expansive force when in the compressed state.

23. The assembly of claim 22, wherein the resistance to elastic deformation of the sheath is greater than the expansive force exhibited by the deformable member.

24. The assembly of claim 23, wherein the resistance to elastic deformation of the sheath is between 1 percent to 5 percent greater than the expansive force exhibited by the deformable member.

25. The assembly of claim 14, further comprising:
a catheter disposed within the lumen of the tubular member with a balloon portion of the catheter lying within the deformable member to expand the deformable member together with the sheath against the vascular wall.

26. The assembly of claim 9, wherein the deformable member is embedded within the sheath.

27. The assembly of claim 26, wherein the deformable member is a wire coil.

28. The assembly of claim 26, wherein the deformable member is a stent.

29. A method for entrapping plaque particles against a vascular wall at a predetermined intravascular site, comprising the steps of:

providing a radially outwardly deformable, tubular sheath having a proximal end and a distal end;

5 providing an intravascular deployment catheter having a proximal end, a distal end, and a lumen extending therebetween;

attaching the sheath proximal end to the deployment catheter distal end;

introducing the deployment catheter into the vasculature;

10 advancing the deployment catheter through the vasculature to position the sheath at the intravascular site; and

expanding the sheath against the vascular wall at the intravascular site to trap the plaque therebetween.

30. The method of claim 29, wherein the sheath is formed as a unitary part of a distal tip of the deployment catheter.

31. The method of claim 29, wherein the step of providing an intravascular deployment catheter comprises providing an intravascular deployment catheter having a plurality perforations formed near the distal end of the deployment catheter to allow fluid communication between the outside of the deployment catheter and the
5 deployment catheter lumen.

32. The method of claim 29, wherein the sheath is comprised of a material selected from the group of materials consisting of polymers, cross-linked materials, and composites.

33. The device of claim 32, wherein the sheath material has a yield strength of between 50 psi and 300 psi.

34. The method of claim 33, wherein the sheath material has a break point tensile strength of over 2000 psi.

35. The method of claim 29, comprising, prior to the step of introducing the deployment catheter, the further steps of:

providing a radially outwardly deformable, tubular member;

disposing the deformable member within the sheath; and wherein

5 the step of expanding the sheath comprises expanding the deformable member along with the sheath, the sheath contacting the vascular wall and the deformable member contacting the sheath.

36. The method of claim 35, wherein the deformable member is a wire mesh.

37. The method of claim 35, wherein the deformable member is a stent.

09885438-064501
105199-9945860

1. 1990-1991 2. 1991-1992 3. 1992-1993 4. 1993-1994 5. 1994-1995 6. 1995-1996 7. 1996-1997 8. 1997-1998 9. 1998-1999 10. 1999-2000 11. 2000-2001 12. 2001-2002 13. 2002-2003 14. 2003-2004 15. 2004-2005 16. 2005-2006 17. 2006-2007 18. 2007-2008 19. 2008-2009 20. 2009-2010 21. 2010-2011 22. 2011-2012 23. 2012-2013 24. 2013-2014 25. 2014-2015 26. 2015-2016 27. 2016-2017 28. 2017-2018 29. 2018-2019 30. 2019-2020 31. 2020-2021 32. 2021-2022 33. 2022-2023 34. 2023-2024 35. 2024-2025 36. 2025-2026 37. 2026-2027 38. 2027-2028 39. 2028-2029 40. 2029-2030 41. 2030-2031 42. 2031-2032 43. 2032-2033 44. 2033-2034 45. 2034-2035 46. 2035-2036 47. 2036-2037 48. 2037-2038 49. 2038-2039 50. 2039-2040 51. 2040-2041 52. 2041-2042 53. 2042-2043 54. 2043-2044 55. 2044-2045 56. 2045-2046 57. 2046-2047 58. 2047-2048 59. 2048-2049 60. 2049-2050 61. 2050-2051 62. 2051-2052 63. 2052-2053 64. 2053-2054 65. 2054-2055 66. 2055-2056 67. 2056-2057 68. 2057-2058 69. 2058-2059 70. 2059-2060 71. 2060-2061 72. 2061-2062 73. 2062-2063 74. 2063-2064 75. 2064-2065 76. 2065-2066 77. 2066-2067 78. 2067-2068 79. 2068-2069 80. 2069-2070 81. 2070-2071 82. 2071-2072 83. 2072-2073 84. 2073-2074 85. 2074-2075 86. 2075-2076 87. 2076-2077 88. 2077-2078 89. 2078-2079 90. 2079-2080 91. 2080-2081 92. 2081-2082 93. 2082-2083 94. 2083-2084 95. 2084-2085 96. 2085-2086 97. 2086-2087 98. 2087-2088 99. 2088-2089 100. 2089-2090 101. 2090-2091 102. 2091-2092 103. 2092-2093 104. 2093-2094 105. 2094-2095 106. 2095-2096 107. 2096-2097 108. 2097-2098 109. 2098-2099 110. 2099-2100 111. 2100-2101 112. 2101-2102 113. 2102-2103 114. 2103-2104 115. 2104-2105 116. 2105-2106 117. 2106-2107 118. 2107-2108 119. 2108-2109 120. 2109-2110 121. 2110-2111 122. 2111-2112 123. 2112-2113 124. 2113-2114 125. 2114-2115 126. 2115-2116 127. 2116-2117 128. 2117-2118 129. 2118-2119 130. 2119-2120 131. 2120-2121 132. 2121-2122 133. 2122-2123 134. 2123-2124 135. 2124-2125 136. 2125-2126 137. 2126-2127 138. 2127-2128 139. 2128-2129 140. 2129-2130 141. 2130-2131 142. 2131-2132 143. 2132-2133 144. 2133-2134 145. 2134-2135 146. 2135-2136 147. 2136-2137 148. 2137-2138 149. 2138-2139 150. 2139-2140 151. 2140-2141 152. 2141-2142 153. 2142-2143 154. 2143-2144 155. 2144-2145 156. 2145-2146 157. 2146-2147 158. 2147-2148 159. 2148-2149 160. 2149-2150 161. 2150-2151 162. 2151-2152 163. 2152-2153 164. 2153-2154 165. 2154-2155 166. 2155-2156 167. 2156-2157 168. 2157-2158 169. 2158-2159 170. 2159-2160 171. 2160-2161 172. 2161-2162 173. 2162-2163 174. 2163-2164 175. 2164-2165 176. 2165-2166 177. 2166-2167 178. 2167-2168 179. 2168-2169 180. 2169-2170 181. 2170-2171 182. 2171-2172 183. 2172-2173 184. 2173-2174 185. 2174-2175 186. 2175-2176 187. 2176-2177 188. 2177-2178 189. 2178-2179 190. 2179-2180 191. 2180-2181 192. 2181-2182 193. 2182-2183 194. 2183-2184 195. 2184-2185 196. 2185-2186 197. 2186-2187 198. 2187-2188 199. 2188-2189 200. 2189-2190 201. 2190-2191 202. 2191-2192 203. 2192-2193 204. 2193-2194 205. 2194-2195 206. 2195-2196 207. 2196-2197 208. 2197-2198 209. 2198-2199 210. 2199-2200 211. 2200-2201 212. 2201-2202 213. 2202-2203 214. 2203-2204 215. 2204-2205 216. 2205-2206 217. 2206-2207 218. 2207-2208 219. 2208-2209 220. 2209-2210 221.	
--	--

45. The method of claim 43, wherein the deformable member is a wire coil.

46. The method of claim 29, comprising, following the step of expanding the sheath, the further steps of:

providing a delivery catheter having a proximal end and a distal end and a lumen extending therebetween;

5 providing a self-expanding intravascular device having a proximal end and a distal end and further having a compressed state and an expanded state;

placing the intravascular device in its compressed state within the delivery catheter distal end;

10 introducing the delivery catheter into the lumen of the deployment catheter;

advancing the delivery catheter through the lumen of the deployment catheter to position the distal end of the delivery catheter adjacent the distal end of the sheath;

15 partially retracting the delivery catheter to allow the distal end of the intravascular device to expand against the vessel wall at a location distal of the plaque at the intravascular site;

withdrawing the sheath proximally from the intravascular site to expose the distal end of the delivery catheter;

20 retracting the delivery catheter to allow the entire intravascular device to expand against the vessel wall at the intravascular site and trap the plaque therebetween;

withdrawing the delivery catheter from within the intravascular catheter; and

25 withdrawing the intravascular catheter and the sheath from within the vasculature.

47. The method of claim 46, wherein:

the steps of advancing the intravascular device out of the delivery catheter comprise withdrawing the delivery catheter proximally along the pusher rod to expose the intravascular device and thereby allow it to assume its expanded state.

49. The method of claim 48, wherein the stent is formed with a plurality of apertures, each aperture being no larger than 200 microns across when the stent is in the expanded state.

51. The method of claim 50, wherein the wire mesh is formed with a plurality of apertures, each aperture being no larger than 200 microns across when the wire mesh is in the expanded state.

the step of expanding the sheath against the vascular wall comprises partially expanding the sheath; and comprising, after the step of withdrawing the delivery catheter, the further steps of:

5 providing a balloon catheter;

inserting the balloon catheter into the lumen of the deployment catheter;
advancing the balloon catheter to position the balloon within the
intravascular device;

inflating the stent to further expand the intravascular device against the
10 vessel wall and entrap the plaque therebetween; and
withdrawing the balloon catheter from the deployment catheter lumen.

53. The method of claim 46, wherein the step of providing a delivery catheter
comprises providing a delivery catheter with perforations formed near the distal end of
the delivery catheter to allow fluid communication between the outside of the delivery
catheter and the delivery catheter lumen.

54. An assembly for trapping arterial plaque against a vascular wall,
comprising:

a deployment catheter having a proximal end, a distal end, and an inner
lumen extending therebetween;

5 a radially outwardly, deformable, tubular sheath to be introduced
intravascularly and expanded against the vascular wall to entrap the plaque
therebetween, the sheath having a proximal end attached to the deployment catheter
distal end, and a distal end;

a delivery catheter being axially movably disposed within the deployment
10 catheter lumen and having a distal end and an inner lumen;

a self-expanding intravascular device disposed within the delivery
catheter lumen adjacent the delivery catheter distal end;

an outer sheath disposed over the deployment catheter to receive the
deformable sheath therein; and

15 a pusher rod axially movably disposed within the delivery catheter lumen
proximal of the intravascular device.

FOIA b 7 - DEXTER

- | Table 1. Demographic characteristics of the study population | |
|--|-------------|
| Age (years) | Mean (SD) |
| Male | 55.2 (10.5) |
| Female | 56.8 (11.2) |
| Marital status | |
| Married | 78.5% |
| Single | 21.5% |
| Education level | |
| High school or above | 65.2% |
| Below high school | 34.8% |
| Occupation | |
| White collar | 45.1% |
| Blue collar | 54.9% |
| Income (USD/month) | |
| < 1000 | 12.3% |
| 1000-2000 | 35.7% |
| 2000-3000 | 28.9% |
| > 3000 | 23.1% |
| Health insurance | |
| Yes | 89.4% |
| No | 10.6% |
| Smoking status | |
| Smoker | 28.7% |
| Non-smoker | 71.3% |
| Alcohol consumption | |
| Regular | 15.6% |
| Occasional | 32.4% |
| Never | 52.0% |